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Randomized Prospective Study of Endoscopic Rubber Band Ligation Compared With Bipolar Coagulation For Chronically Bleeding Internal Hemorrhoids

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ABSTRACT

OBJECTIVES: Our purpose was to compare the efficacy, complications, success rate, recurrence rate at 1 year, and crossovers of rubber band ligation (RBL) with those of bipolar electrocoagulation (BPEC) treatment for chronically bleeding internal hemorrhoids.

METHODS: A total of 45 patients of mean age 51.5 years, who had rectal bleeding from grade II or III hemorrhoids and in whom intensive medical therapy failed, were randomized in a prospective study comparing RBL with BPEC. Treatment failure was predefined as continued bleeding, occurrence of a major complication, or failure to reduce the size of all internal hemorrhoidal segments to grade I in ≤ 3 treatments. Patients were followed up for 1 year.

RESULTS: With similar patients, rectal bleeding and other symptoms were controlled with significantly fewer treatments of RBL than of BPEC (2.3±0.2 vs. 3.8±0.4, P < 0.05), and RBL had a significantly higher success rate (92% vs. 62%, P< 0.05). RBL had more cases of severe pain during treatment (8% vs. 0%, P> 0.05), but significantly fewer failures and crossovers (8% vs. 38%). Symptomatic recurrence at 1 year was 10% RBL and 15% BPEC.

CONCLUSIONS: For patients with chronically bleeding grade II or III internal hemorrhoids that are unresponsive to medical therapy, safety and complication rates of banding and BPEC were similar. The success rate was significantly higher with RBL than with BPEC. Symptom recurrence rates at 1 year were similar.

KEYWORDS :

INTRODUCTION

Non-operative techniques for ablating hemorrhoids include sclerotherapy, rubber band ligation (RBL), infrared photocoagulation, direct current coagulation, bipolar electrocoagulation (BPEC), and heater probe thermocoagulation. Each of these non-operative therapies can be safely carried out on an outpatient basis. None of the therapies require conscious sedation, and complications are infrequent and usually minor. Endoscopic treatment is most appropriate for grades II and III internal hemorrhoids, but is also indicated when medical treatment of grade I hemorrhoids has failed.

Rubber band ligation is now more commonly used than sclerotherapy. Ligation causes focal ischemic necrosis, ulceration, and scarring, which results in fixation of the connective tissue to the rectal wall. Earlier studies have shown that RBL is the most effective non-operative treatment with the fastest obliteration rate and the lowest recurrence rate. However, more discomfort was reported than with other techniques.

Bipolar electrocoagulation is one of the most effective coagulation techniques for internal hemorrhoid treatment. It causes coagulation, occlusion, sclerosis, and fibrosis of the internal hemorrhoidal tissue. The procedure is fast and has relatively few complications, which are usually minor. Several studies have compared BPEC with other types of coagulation.

In randomized prospective trials comparing BPEC with direct current coagulation, the BPEC treatments were significantly more comfortable, took less time, and resulted in fewer recurrences, but had more complications. In another randomized prospective comparative study of bipolar coagulation vs. heater probe, the techniques and complications of the two treatments were reported to be similar. However, although bipolar coagulation caused less pain during the treatment than the heater probe, it also resulted in a greater number of treatment failures and required more treatment sessions for symptomatic relief. In another randomized comparison of infrared coagulation with bipolar coagulation, there was no significant difference in complications or number of treatments required to relieve internal hemorrhoidal symptoms, including bleeding.

To our knowledge, there have been no earlier randomized studies reported that compare the relative risks and benefits of RBL vs. bipolar coagulation for the treatment of bleeding from internal hemorrhoids. Our purposes in this randomized prospective study were to assess whether RBL obliterated internal hemorrhoids more rapidly than bipolar coagulation, and whether RBL was as safe and well tolerated as bipolar coagulation for patients with chronic bleeding from internal hemorrhoids. Durability of treatments and recurrence of hemorrhoidal bleeding or other symptoms were also evaluated at 1 year.

METHODS

This randomized study of endoscopic RBL vs. anoscopic BPEC for internal hemorrhoids was carried out at the GCS Medical College n Research center. The specific aims of this study were: (i) to compare the efficacy of endoscopic band ligation vs. BPEC for the treatment of patients with chronic bleeding from grades II and III internal hemorrhoids, (ii) to evaluate the safety and tolerability of the two different treatments, and (iii) to evaluate the durability of treatment effect and recurrence of symptoms at 1 year. All patients enrolled into this study met all of the following inclusion criteria: (i) grade II or III internal hemorrhoids with chronic rectal bleeding, which failed at least 8 weeks of intensive medical therapy, (ii) age over 18 years, (iii) a life expectancy of at least 24 months, and (iv) a signed written informed consent.

Patients were excluded from the study if any one of the following were present: (i) the patient was uncooperative, unable to sign a written informed consent, or could not return for routine outpatient follow-up, (ii) severe or end-stage comorbid illness, including cirrhosis, portal hypertension, severe renal or respiratory failure, sepsis, active

rectal inflammatory bowel disease, and acquired immune deficiency syndrome, (iii) earlier endoscopic (e.g., sclerotherapy, ligation, etc.) or surgical (e.g., hemorrhoidectomy) treatment of hemorrhoids within the past 6 months, (iv) ongoing need for anticoagulation therapy (with warfarin or heparin) or high doses of aspirin and/or non-steroidal anti-inflammatory agents, (v) presence of severe rectal pain, (vi) only grade I or presence of grade IV internal hemorrhoids, (vii) recently thrombosed internal or external hemorrhoids, (viii) anal stricture, fissure, fistula, or abscess, (ix) rectal carcinoma or bleeding distal colonic polyp, (x) rectal varices, (xi) acute or chronic colitis, (xii) rectal prolapse, (xiii) radiation telangiectasia of the rectum, (xiv) coagulopathy defined as a prothrombin time >3 s over control (INR (international normalized ratio) >1.3), or (xv) thrombocytopenia defined as a platelet count < 75,000.

Sample size estimate

A sample size estimate was made on the basis of our earlier experience with RBL and BPEC for the number of treatment sessions to completely control rectal bleeding. This was expected to be a mean of two treatment sessions for RBL vs. four sessions with BPEC. For 80% power, an alpha of 0.05, and two-sided comparison, 14 patients per group were the estimated sample size. To obviate any problems with potential dropouts, inaccuracy of this estimate, and to insure adequate numbers of patients for the analyses of secondary outcomes, we sought to randomize approximately 45 patients, or 21–24 patients per treatment group.

ASSESSMENT, RANDOMIZATION, AND HEMORRHOIDS TREATMENT DEVICES AND TECHNIQUES

All patients who were referred to investigators for evaluation of rectal bleeding underwent an initial sigmoidoscopy, or colonoscopy and anoscopy for evaluation of rectal bleeding After patients met the inclusion and exclusion criteria and signed a written informed consent, the treatment was determined by opening a sealed envelope at the time of the slotted anoscopy, which randomized patients to one of two treatment groups: (i) endoscopic RBL, or (ii) BPEC.

Patients randomized to endoscopic RBL were treated with a diagnostic video endoscope fitted with a single-shot ligating device or multi-shot device Rubber band ligation was carried out with the endoscope in an end-on and/or retroflexed position similar in technique to esophageal variceal ligation and junctional gastric variceal ligation. The majority of treatments were carried out using the single-shot device. A maximum of four internal hemorrhoids were banded ≥ 1 cm above the dentate line during each session. Treatments were repeated every 4–6 weeks until relief of bleeding and reduction of all internal hemorrhoids to grade 0 or I.

Patients randomized to bipolar coagulation therapy had a maximum of four hemorrhoid segments treate ≥ 1 cm above the dentate line using a rigid probe with 1 s pulses at a 16 watt setting through a slotted anoscope. Treatments were repeated at 4- to 6 -week intervals until relief of bleeding and reduction of all internal hemorrhoids to grade 0 or I.

PAIN RATINGS, FOLLOW-UP, AND SUCCESS/FAILURE RATINGS

After each session, patients filled out a questionnaire form using a 10-cm visual analog scale to assess the level of pain associated with the treatment. Patients were instructed to continue intensive medical management with daily warm water seitz baths, stool softeners, fiber supplementation, and hydrocortisone-based creams (RBL) or hydrocortisone suppositories (bipolar group) as needed (for swelling, pressure, mild pain, or bleeding) during the first week after these treatments. Patients were also advised to notify the research coordinator if they developed severe rectal pain, bleeding, fevers, or chills.

Study end points were control of all (both severe and on toilet tissue) rectal bleeding, a severe complication or refusal to continue the treatment, and reduction of all internal hemorrhoid segments to grade 0 or I in three or less treatment sessions. These end points were monitored and independently recorded on study forms by a research study coordinator. She first clarified any questions with the patient, primary care physician, or endoscopist.

After achieving the treatment end points, all patients were followed up by the gastroenterologist and/or study coordinator once every 3 months for a total of at least 12 months to assess the recurrence of internal hemorrhoidal symptoms and change in size of internal hemorrhoids. Symptomatic recurrences were treated medically, and if this failed, anoscopic re-treatment was carried out.

Treatment failures for this study were predefined as: (i) a major complication of treatment (e.g., severe rectal pain requiring analgesics or severe bleeding, i.e., fall in baseline hematocrit ≥ 5%; anal stricture; or rectal abscess), or (ii) unresponsiveness to therapy, defined as failure to reduce all internal hemorrhoid segments to grade I or less after three treatment sessions. Patients who failed treatment were taken off the study and given the choice of either crossover and treatment with the other therapy (e.g., bipolar probe or RBL), or treatment with any current medical, endoscopic, or surgical therapies.

RESULTS

Baseline and initial results

From May 2013 to May 2014, 100 patients with chronic rectal bleeding suspected to be from internal hemorrhoids were assessed for this study. A total of 55 patients were excluded. A total of 45 patients of mean age 51.5 years, with bleeding grade II or III internal hemorrhoids, were enrolled into this prospective randomized trial comparing RBL (24 patients) vs. bipolar coagulation (21 patients). Background variables are shown in Table 1. The two treatment groups were comparable with respect to age (53±3 vs. 50±3 years), gender (54% vs. 71% men), and duration of chronic, recurrent rectal bleeding before randomization (9±2 vs. 8±2 years) for RBL and bipolar coagulation, respectively. Hemorrhoid grade was somewhat more advanced in patients treated with bipolar coagulation (29% grade II, 71% grade III) than with RBL (42% grade II, 56% grade III), although these differences were not statistically significant.

The patients in the RBL treatment group and bipolar coagulation treatment group had similar symptoms at the time they were randomized. All patients had recurrent rectal bleeding. Concomitant hemorrhoidal prolapse and rectal discomfort occurred in 41–62% of all patients. Perirectal itching and soiling were reported in 13–33% of patients.

Treatment results and follow-up

Rubber band ligation was more effective than bipolar coagulation in controlling bleeding and reducing the hemorrhoid size (92% vs. 62%, respectively, $P < 0.05$) within three treatment sessions. Furthermore, RBL required significantly fewer treatment sessions (2.3±0.2 sessions) than bipolar coagulation therapy (3.8±0.4 sessions) to control the bleeding ($P < 0.05$).

Eight patients (38%) treated with bipolar coagulation failed to achieve the treatment end points within three sessions because of ongoing rectal bleeding or persistent hemorrhoidal prolapse (grade ≥ II). All of these patients were crossed over to RBL, which controlled bleeding or prolapse after 1–2 treatments. No patients were crossed over from RBL to bipolar coagulation. No patients required surgical hemorrhoidectomy in this study.

The complication rate was low for both treatments. Two patients (8%) treated with RBL and no patients treated with bipolar coagulation had moderately severe rectal pain, requiring oral narcotic analgesics, but not hospitalization ($P > 0.05$). No one in either group had other severe complications such as perirectal abscess, anal fissure, or rectal stenosis. Mild complications were in similar frequency in both groups (4% in RBL group, 5% in bipolar group). Median pain scores collected from our questionnaire using a 10-cm visual analog scale were not different between the two groups (see Table 4). Only during the second treatment session was the pain score higher in the RBL group than in the bipolar coagulation group.

Once the bleeding was controlled and the internal hemorrhoids were reduced to grade I or less in size, other symptoms were also controlled. However, with internal hemorrhoid enlargement, bleeding, prolapse, and pain recurred more oft en than itching or soiling. The rate of recurrent internal hemorrhoid symptoms (rectal bleeding and/or hemorrhoidal prolapse) was low in both treatment groups. At a mean follow-up period of 50 weeks, the respective rates for RBL and bipolar probe pretreatment for recurrent internal hemorrhoidal

symptoms or bleeding were 10 and 15%. These symptoms were easily controlled with 1–2 repeat anoscopic treatments in all patients with recurrence

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